



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

November 14, 2000

Our Reference: 2918785

Louie L. Brodeth, President
Brosan Inc., dba Simex International
101 Associated Road
South San Francisco, California 94080

WARNING LETTER

Dear Mr. Brodeth:

We inspected your seafood firm on May 5 and 10, 2000. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110). The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

We found that your firm has serious HACCP deficiencies. These deficiencies cause your frozen vacuum packed smoked fish, specifically, smoked deboned milkfish, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with Mr. Noy E. Santander, Vice President, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP violations are as follows:

1. You must have written product specifications that are designed to ensure that the fish and fishery products that you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, during the inspection of May 5 and 10, 2000, we found, for example, that you did not have product specifications for vacuum packed smoked deboned milkfish from the Philippines, to address the potential food safety hazard of pathogen growth and toxin formation.
2. You must implement an affirmative step that ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not satisfactorily fulfill the affirmative step required in 21 CFR 123.12(a)(2)(ii)(D). Specifically, there was no written guarantee from the foreign processor that the frozen vacuum packed smoked deboned milkfish was processed in accordance with the requirements of the seafood HACCP regulations.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert, and future shipments of the product may be subject to detention without physical examination.

Please respond in writing within fifteen working days from receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response, documentation such as copies of product specifications, verification plans, your foreign processors' HACCP plans, or other useful information that would assist us in evaluating your corrections. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Roger L. Lowell", is written over a large, loopy circular flourish.

Roger L. Lowell
Acting Director
San Francisco District

Enclosure

cc: Mr. Noy E. Santander, Vice President